K022331

510(k) Summary of Safety and Effectiveness

The following information provides data supporting a substantially equivalent determination between the revised ADVIA 120 cerebrospinal fluid (CSF) method and the current ADVIA 120 CSF method (K003796).

Intended Use

The ADVIA 120 cerebrospinal fluid (CSF) cell count is intended to provide an *in vitro* diagnostic, quantitative determination of blood cells in CSF specimens analyzed in the manual open tube mode. The ADVIA 120 provides leukocyte (WBC) and erythrocyte (RBC) counts along with both absolute and proportional counts for the WBC differential.

Device Description

The revised ADVIA 120 CSF method consists of the following changes to the ADVIA 120 Hematology System.

1. A reformulated reagent that can be used to obtain CSF counts from a single optical channel of the ADVIA 120 system.
2. Revised software to calculate the cell counts.
3. A software key to selectively allow access to the CSF mode of the system software.
4. Control products to maintain quality control of the CSF method.

The following parameters are reported with the ADVIA 120 CSF method:

White Blood Cell Parameters
WBC - white blood cell count
Neut - neutrophil count (percentage and absolute counts)
Lymph - lymphocyte count (percentage and absolute counts)
Mono - monocyte count (percentage and absolute counts)
Eos* – eosinophil count (percentage and absolute counts)
MN – mononuclear count (percentage and absolute counts)
PMN – polymorphonuclear count (percentage and absolute counts)

Red Blood Cell Parameters
RBC - red blood cell count

* For Laboratory Use Only (not reportable)

Principles of Operation

The CSF sample is mixed by manual dilution with ADVIA 120 CSF Reagent which isovolumetrically spheres and fixes the cells. After a 4-minute incubation period, the prepared sample is then aspirated directly into the ADVIA 120 system. The cells are then detected and enumerated based on light scatter and absorbance measurements using the ADVIA 120 laser optics. A scatter versus scatter and scatter versus absorbance cytogram is displayed with the thresholds and results automatically calculated for each sample

Similarities and Differences between the revised ADVIA 120 CSF Method and the ADVIA 120 CSF Predicate Method (K003796)

The following table provides similarities and differences between the revised ADVIA 120 CSF method and the predicate method.

Similarities/Differences	Characteristic	Predicate Method	Revised Method
Similarities	Intended Use	To provide a quantitative determination of blood cells in CSF specimens.	Same as predicate method.
	Specimen Analyzed	CSF collected in a sterile specimen tube.	Same as predicate method.
Differences	WBC Count	Automated dilution with cell count performed in the basophil channel of the ADVIA 120. RBCs are lysed in the reaction.	Manual dilution with cell counts performed using RBC optics. RBCs are not lysed.
	RBC Count	Automated dilution with cell count performed in RBC/Plt channel of the ADVIA 120.	Manual dilution with cell counts performed using RBC optics.
	WBC Differential	Automated dilution with cell count performed in the peroxidase channel of the ADVIA 120. RBCs are lysed and WBCs are differentiated based on morphology and peroxidase activity.	Manual dilution with cell performed using RBC optics. RBCs are not lysed, and WBCs are differentiated based on morphology only.

Conclusion

The test results included in this submission demonstrate that the revised ADVIA 120 CSF method meets the manufacturer's intended specifications and is substantially equivalent to the predicate device.

Date 7/16/02

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Kenneth T. Edds, Ph.D.
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SEP 11 2002

Re: k022331
Trade/Device Name: Cerebrospinal Fluid Method for the Advia 120 Hematology Analyzer
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated cell counter
Regulatory Class: II
Product Code: GKL, GKZ, JPK
Dated: August 28, 2002
Received: August 29, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022331

Device Name: Cerebrospinal Fluid Method for the Advia 120 Hematology Analyzer

Indications for Use: The ADVIA 120 cerebrospinal fluid (CSF) cell count is intended to provide an *in vitro* diagnostic, quantitative determination of blood cells in CSF specimens analyzed in the manual open tube mode. The ADVIA 120 provides leukocyte (WBC) and erythrocyte (RBC) counts along with both absolute and proportional counts for the WBC differential.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022331

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)